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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/562,142

12/23/2005

Thomas Bar

27097U

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34375 7590 11/19/2010

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Alexandria, VA 22314

EXAMINER

DESAI, RITA J

ART UNIT

PAPER NUMBER

1625

MAIL DATE

DELIVERY MODE

11/19/2010

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/562,142	<b>Applicant(s)</b> BAR ET AL.	
	<b>Examiner</b> Rita J. Desai	<b>Art Unit</b> 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 9/30/10.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-7,9-11,13,14 and 16-21 is/are pending in the application.
- 4a) Of the above claim(s) 9-11,14 and 17-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7,13 and 16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

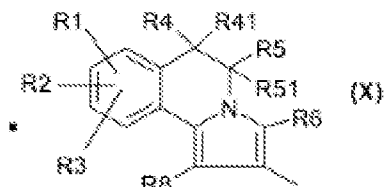
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**DETAILED ACTION**

Claims 1-7, 9-11, 13, 14, 16-21 are pending.

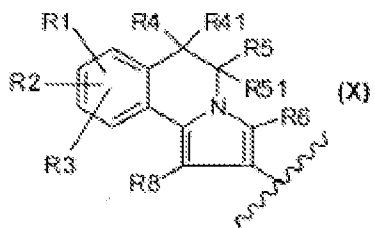
Claims in group I of the restriction drawn to compounds of formula X was elected.

Group I, claim(s) 1-7, 13, 16 drawn to compounds of the formula X wherein none of the R's form an additional ring.



Formula X was given by

The claims have now been amended to be compounds of formula X given by



Thus the structure has been modified to be a complex with an attachment.

Claim 16 has also been modified to insert certain steps (product by process claim).

Claims under examination are claims 1-7, 13 and 16 drawn to compounds.

Response to the arguments:-

The rejections under 35 USC 103 over

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1)

over Bauser et al. (WO 03/014116), Zhang et al. (WO 03/51877) and Niewohner et al. (WO 02/048144) in view of GB 1153670, US 4694085 and Liebigs Ann. Chem. 9, 1534-1544 (1981).

2) over Casagrande et al. and

3) the rejection over Anderson et al.

All still stand. The declaration teaches specific compounds with a phenyl group which are drawn to compounds of the formula Ic not within the scope of formula X as X formula has a CH<sub>3</sub> instead of an R<sup>7</sup> group. The formula in the claim is not clearly represented. It has now been changed from CH<sub>3</sub> to be attached to some other group which is no longer the compounds of formula X as given in the specifications.

The rejection under 35 USC 112 however still stands.

Applicants argue that the claims have been amended so that R<sub>2</sub> and R<sub>3</sub> cannot be H at the same time. The claim is drawn to compounds of formula X which in the specification never includes R<sub>2</sub> to be an Hydrogen. The arguments refer to different subaspects of formula Xa and Xb not of X. Thus the addition of R<sub>2</sub> to be a h in the formula X claim 1 would constitute new matter.

The rejection under 35 USC 112 2<sup>nd</sup> para also still stands.

Applicants arguments incorporate various foreign documents to show how to make them. This is improper incorporation by reference. The incorporation of essential material in the specification by reference to an unpublished U.S. application, foreign application or patent, or to a publication is improper. Applicant is required to amend the disclosure to include the material incorporated by reference, if the material is relied upon to overcome any objection, rejection, or

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other requirement imposed by the Office. The amendment must be accompanied by a statement executed by the applicant, or a practitioner representing the applicant, stating that the material being inserted is the material previously incorporated by reference and that the amendment contains no new matter. 37 CFR 1.57(f).

Additionally applicants change in the structure of the compounds leads to other 112 issues which are given below.

It is unclear what it is attached to.

The claims recites “ which inhibits PDE10 comprising a structural element as an integral part of an overall structure”

The phrases beginning “which inhibits PDE10 comprising a structural element as an integral part of an overall structure” are unduly functional. Names, structures, and chemical formulas precisely define organic molecules. Attempting to define structure by function is not proper when the structures can be clearly expressed in terms that are more precise. It is not sufficient to define a chemical structure solely by its principal biological property. Applicants are attempting to define the structure of a claimed molecule by a single property. The U.S. Patent and Trademark Office, Board of Patent Appeals and Interferences held in *Ex parte Pulvari* 157 USPQ 169 that “a material defined, as here, solely in terms of what it can do, of a property thereof or of the scientific principle that underlies that property ... does [not] particularly point out, as required by 35 U.S.C. 112, appellant's disclosed invention”.

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Claim 16 does not give any of the steps required to make the compounds without undue experimentation.

The term "selecting intellectually a structure "would require an undue amount of experimentation to a person of ordinary skill in the art. Further in step B) "modifying intellectually said selected structure in such a way that the modified structure comprises" also requires an undue amount of experimentation to make the compound.

Note:

Applicants current formula X as given in the claim is not fully supported by the spec.

The formula Xa and Xb are not clear subsets of X as the definition of R2 is not the same.

The formula of X as now given in the claim has to be attached to something else which is not clearly defined.

The formula Ic has support in the spec and also the declaration is a comparison of these compounds.. Formula Ic is not a subset of X because of the R7.

If applicants amend the claim to formula Ic and amend the claim language, including the one in claim 16, ( to delete the functional language,) it would place the claims in a better condition for allowance.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rita J. Desai whose telephone number is 571-272-0684. The examiner can normally be reached on Monday - Friday, flex time..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Rita J. Desai/  
Primary Examiner, Art Unit 1625

November 16, 2010.